

### REMARKS

Reconsideration of this application in view of the following remarks is respectfully requested.

## Status of the Claims

Upon entry of the amendments, Claims 1-6 and 8-11 are pending. Claim 7 has been cancelled without prejudice. Applicants reserve the right to file one or more divisional or continuation applications directed to any cancelled subject matter or any other subject matter disclosed in the application, which is not encompassed by the pending claims. Claim 1 has been amended to incorporate the limitations of original claim 7. No new matter has been added.

### Rejection Under 35 U.S.C. §102(b)

Claims 1-3 and 7-11 have been rejected under 35 U.S.C. §102(b) as anticipated by United States Patent No. 4,136,193 (“Bogeso”). Applicants respectfully traverse the rejection.

Claim 1 has been amended to recite that the roller compacted granulate has a median particle size of at least 40 µm. Bogeso does not disclose or suggest a solid unit dosage form containing a roller compacted granulate of citalopram or a pharmaceutically acceptable salt thereof having a median particle size of at least 40 µm. Accordingly, Bogeso does not anticipate claim 1-3 and 8-11, and applicants respectfully request withdrawal of this rejection.

## Rejections Under 35 U.S.C. § 103

Claims 1-11 have been rejected under 35 U.S.C. §103(a) as obvious over Bogeso. The Examiner contends that the determination of a therapeutic dosage as well as modes and methods of administration is well within the purview of the skilled artisan.

In order to properly determine a prima facie case of obviousness, an examiner “must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” M.P.E.P. §2142. This is important,

as “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” *Id.* Three basic criteria must then be met: first, there must be some suggestion or motivation to modify or combine the cited references; second, there must be a reasonable expectation of success; and third, the prior art references must teach or suggest all the claim limitations. M.P.E.P. §2143. With regard to the first criterion, it is important to recognize that the “mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” M.P.E.P. §2143.01 (*citing In re Mills*, 916 F.3d 680 (Fed. Cir. 1990)).

As stated above, Bogeso is silent with respect to the particle size of the citalopram disclosed. Bogeso clearly does not teach or suggest the particle size limitations of the instant claims. Bogeso also does not provide a reasonable expectation that a citalopram granulate having the claimed median particle size could be prepared. Furthermore, Bogeso does not disclose or suggest roller compacting citalopram.

Additionally, applicants have surprisingly and unexpectedly discovered that roller-compacted citalopram has superior flow characteristics due to its larger particle size (*See*, page 3-4 of the specification). This surprising increase in flow characteristics results in better dosing accuracy (*See*, page 4, line 14 of the specification).

For the reasons discussed above, the claims are not obvious over Bogeso. Accordingly, withdrawal of the rejection is requested.

### **The Provisional Rejections for Obviousness-type Double Patenting**

Claims 1-11 have also been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over (1) claims 1-12 of copending application No. 09/730,490, (2) claims 1, 5, 12, 13, 36, 37, and 41-43 of copending application No. 09/730,380, (3) claims 64, 65, 67, 69-74, 99-103, and 105-108 of copending application No. 10/245,824, (4) claims 1-18 of copending application No. 10/310,621, (5) claims 1 and 14 of copending application No.

10/706,886, (6) claims 13-20 of copending application No. 10/741,553, and (7) claims 21-25 and 30-39 of copending application No. 10/750, 049.

U.S. Serial No. 09/730,490 has been abandoned.

As the remaining double patenting rejections are *provisional*, applicants respectfully decline to respond to the rejection at this time. Applicants agree to submit the appropriate terminal disclaimers should the Examiner maintain the rejection upon a finding of allowable subject matter in the present application.

## CONCLUSION

In view of the above amendments and arguments, the pending claims in this application are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By Nicholas J. DiCeglie, Jr.  
Nicholas J. DiCeglie, Jr.

Registration No.: 51,615  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant